

**REMARKS**

The present application has been reviewed in light of the Final Office Action dated December 10, 2008. On May 5, Applicant filed an Amendment in response to the Final Office Action. Applicant now requests, however, that the Amendment of May 5, 2009 not be entered and respectfully requests reconsideration and allowance of this application in view of the amendments above and the remarks to follow. Claims 1-27 are currently pending, of which claims 1, 17 and 22 have been amended herein.

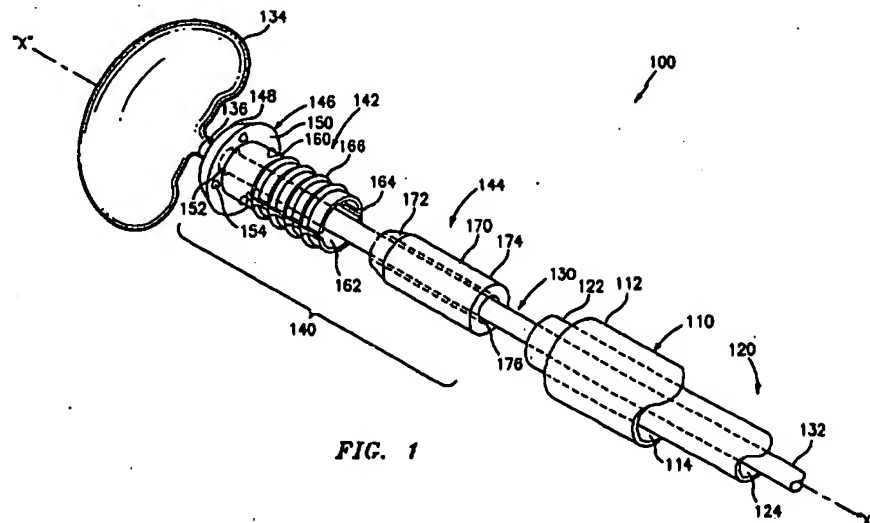
Applicant would like to thank the Examiner for the courtesies extended in a telephone conference conducted on June 2, 2009. The Examiner requested further clarification regarding the separate nature of the flange member and the locking member. The present amendments and remarks reflect this understanding.

Claims 1-6, 8-15, 17-19 and 22-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,206,913 to Yencho et al. (hereinafter Yencho). Applicant respectfully submits that each of independent claims 1, 17 and 22 is allowable over Yencho because Yencho fails to disclose each and every feature of independent claims 1, 17 and 22. Accordingly the rejection of independent claims 1, 17 and 22, under 35 U.S.C. § 102(b) should be withdrawn.

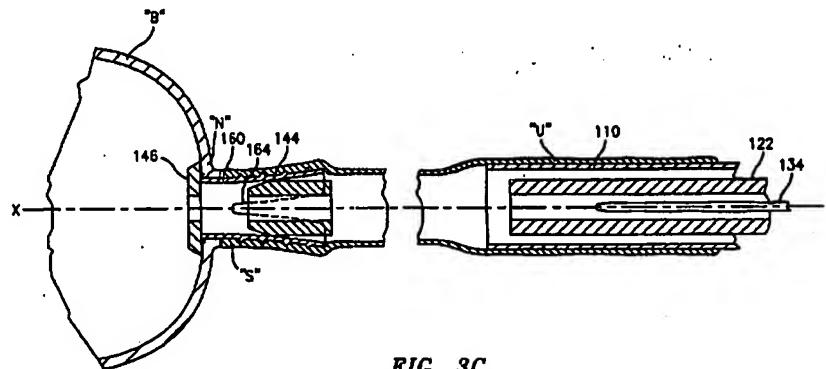
Pursuant to 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131. Applicant respectfully submits that Yencho fails to disclose each and every element recited in each of claims 1, 17 and 22 as required by 35 U.S.C. § 102.

Independent claim 1 recites an apparatus for performing a surgical anastomosis including, *inter alia*, “a flange member having. . . an expandable annular body. . . the annular body defining a passage, the passage extending through. . . the annular body,” and “a locking member configured and dimensioned to be received in the passage of the annular body. Claim 1 also recites that “the annular body of the flange member is movable between an unexpanded configuration when the locking member is outside the passage of the annular body and a radially expanded configuration upon insertion of the locking member into the passage of the annular body.”

The present application describes an embodiment depicted in FIG. 1 below in which apparatus 100 includes a flange member 142 having an expandable annular body 160. The annular body 160 defines a passage 162 extending therethrough. The apparatus 100 also includes a locking member 144 that is configured and dimensioned to be received in the passage 162. Since the locking member 144 is depicted outside the passage 162 in FIG. 1, the annular body 160 of the flange member 142 is in an unexpanded configuration.



The annular body 160 is movable to a radially expanded configuration when the locking member 144 is moved into the passage 162 of the annular body as depicted in FIG. 3c below. As described in paragraph [0058] of the Applicant's specification, "by driving locking member 144 forward, distal end 172 of locking member 144 enters central opening 162 of annular body 160. Further advancement. . . causes the proximal end of annular body 160 to ride or be cammed along distal end 172 to thereby deflect the proximal end of annular body 160 radially outward."



In contrast, Yencho discloses a system for attaching a graft vessel 125 to a target blood vessel 127 by applying a large vessel stent 110 (see FIG. 12 reproduced below). The stent 110 includes a cylindrical body 111, a distal deformable section 115 and a proximal deformable section 116. As illustrated in FIG. 15 and 29 below, the distal deformable section 115 radially expands to form a distal end flange 121 and the proximal deformable section 116 radially expands to form a proximal end flange 122. "The flanges 121, 122 are deployed by circumferentially rotating the proximal end of the stent body relative to the distal end of the stent body" (col. 10, lines 34-36).

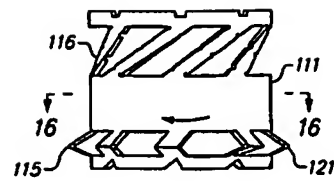
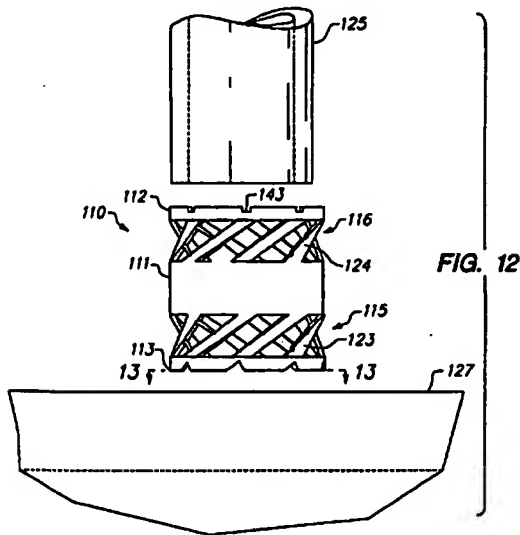


FIG. 15

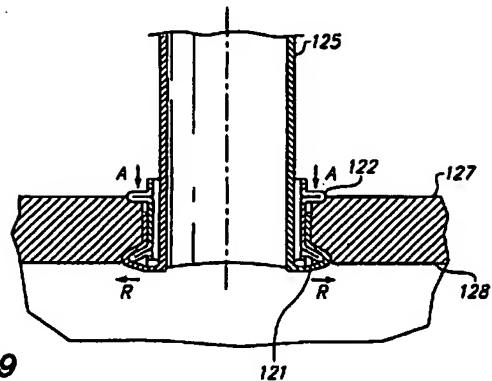


FIG. 29

The Office Action asserts that the flange 122 has an expandable annular body defining a passage. The passage in Yencho is not specifically identified, but reference is made to FIG. 29 (shown above). The Office Action further asserts that the cylindrical portion 111 of Yencho is configured and adapted to radially deflect the expandable annular body portion upon insertion of the cylindrical portion 111 within the passage of the annular body “(where “within” is taken to mean “inside the limits of”).” (See page 3 of the Office Action.) Applicant respectfully disagrees with this characterization of the term “within” as contrary to the plain meaning, as well as the teaching of the specification. However, to facilitate prosecution, Applicant notes that even characterizing the term “within” as suggested by the Office Action, does not cure the deficiencies of the assertions of the Office Action.

The assertion that “within” was taken to mean “inside the limits of” suggests that the cylindrical body 111 is disposed inside some radial or longitudinal limits of the proximal flange 122,

or a passage defined by the proximal flange 122. Even if these limits could be identified, the cylindrical body 111 of Yencho is not within a "passage" defined by the proximal flange. The stent 110 of Yencho includes a lumen 114 extending through the proximal deformable section 116 that forms the proximal flange 122 (see col. 10, lines 1- 12), but this lumen also extends through the cylindrical body 111. The cylindrical body 111 is integral with the proximal flange 122 and the cylindrical body 111 may not be inserted within any passage defined by the proximal flange 122.

Applicant also respectfully disagrees with the assertion of the Office Action that the cylindrical body 111 of Yencho is configured and adapted to radially deflect the expandable annular body portion. Yencho is clear that the flanges 121, 122 are deployed by circumferentially rotating the proximal and distal ends of the stent body as discussed above. The required rotation is achieved with the use of an applicator 131 (see col. 11, lines 45-47). It is clear that the applicator 131 of Yencho is configured to deflect the flange 122 and that the cylindrical body 111 does not deflect the flange 122 as suggested by the Office Action.

Even if the assertions of the Office Action with respect to independent claim 1 were true, independent claim 1, as amended, further recites that "the annular body of the flange member is movable [to] an unexpanded configuration when the locking member is outside the passage." When the stent 110 of Yencho is in the unexpanded configuration depicted above in FIG. 12, the cylindrical body 111 is not outside any passage that it may properly be asserted as being within when the stent 110 is in the expanded configuration of FIG. 29.

In view of the foregoing, Applicant respectfully submits that each and every feature of independent claim 1 is not taught or disclosed by Yencho in that Yencho fails to teach or disclose "a

flange member having. . . an expandable annular body. . . the annular body defining a passage, the passage extending through. . . the annular body,” and “a locking member configured and dimensioned to be received in the passage of the annular body.” Furthermore, Yencho fails to teach or disclose that an “annular body of the flange member is movable between an unexpanded configuration when the locking member is outside the passage of the annular body and a radially expanded configuration upon insertion of the locking member into the passage of the annular body.” Accordingly, Applicant respectfully submits that independent claim 1 is patently distinguishable over Yencho, and therefore allowable over Yencho under 35 U.S.C. § 102(b).

As claims 2-6 and 8-15 depend, directly or indirectly, from claim 1 and contain all of the features of independent claim 1, Applicant respectfully submits that claims 2-6 and 8-15 are also allowable over Yencho under 35 U.S.C. § 102(b).

Independent claim 17 recites a method for performing a surgical anastomosis including the step of, *inter alia*, “advancing the positioning tube through the tubular body to drive and secure the discrete locking member of the anchoring assembly into the annular body of the flange member and to deflect the annular body radially outward.” As discussed above with reference to claim 1, the cylindrical body 111 of Yencho is integral with the flange 122. Thus the cylindrical body 111 of Yencho may not be “secured” into the flange 122 by advancing a positioning tube as called for in independent claim 17. Also, the flange 122 of Yencho is radially expanded by relative rotation of the proximal and distal ends of stent 110 as discussed above with reference to claim 1. Thus, it is the proximal and distal ends of the sent 110 that are driven, and not a discrete locking member as called for in independent claim 17, to radially deflect the flange 122. Thus, the structural elements recited

in independent claim 17 affect the method of independent claim 17 “in a manipulative sense” (see page 12 of the Office Action).

Accordingly, Applicant respectfully submits that independent claim 17 is patently distinguishable over Yencho, and therefore allowable over Yencho under 35 U.S.C. § 102(b). As claims 18-19 depend, directly or indirectly, from claim 17 and contain all of the features of independent claim 17, Applicant respectfully submits that claims 18-19 are also allowable over Yencho under 35 U.S.C. § 102(b).

Independent claim 22 recites “a locking member discrete and separable from the flange member, the locking member . . . being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body such that the locking member is secured within the passage of the annular body.” As discussed above, Yencho discloses a stent 110 including a cylindrical body 111 and a proximal flange member 122. The Office Action asserts that the cylindrical body 111 is discrete from the proximal flange member 122 “(where “discrete” is taken to mean “distinct).” Applicant respectfully disagrees.

The cylindrical body 111 of Yencho is a monolithic or unitary element including the proximal flange member 122. As described at column 10, lines 11 – 12, “the cylindrical body has a distal deformable section 115 and a proximal deformable section 116.” (emphasis added). The proximal deformable section 116 radially expands to the second configuration to “form a proximal end flange 122” (col. 10, line 33). Since the cylindrical body 111 includes the deformable section 116 that forms flange 122, the cylindrical body 111 includes the flange 122. Since the cylindrical

body 111 includes the flange 122, Applicant respectfully submits that the cylindrical body 111 is not discrete from flange member 122.

Applicant recognizes, however, that portions of the cylindrical body 111 may be distinct from the flange member 122. For example, a central non-deformable portion of the cylindrical body 111 that is longitudinally disposed between the distal and proximal deformable sections 115, 116, is recognizably distinct from the flange member 122. Even this central non-deformable portion, however is not “discrete and separable,” from the flange member 122 as called for in independent claim 22. Applicant respectfully submits that Yencho fails to teach or disclose a locking member that is “discrete and separable from the flange member” as recited in independent claim 22.

Accordingly, Applicant respectfully submits that independent claim 22 is patently distinguishable over Yencho, and therefore allowable over Yencho under 35 U.S.C. § 102(b). As claims 23-25 depend, directly or indirectly, from claim 22 and contain all of the features of independent claim 22, Applicant respectfully submits that claims 23-25 are also allowable over Yencho under 35 U.S.C. § 102(b).

Claim 16 stands rejected under 35 U.S.C. § 103(a) over Yencho in view of U.S. Patent No. 6,629,988 to Weadock. Applicant submits that claim 16 is allowable under 35 U.S.C. § 103(a) over Yencho in view of Weadock.

The Examiner relies on Weadock for the disclosure of an anchoring assembly made from a bio-absorbable material. Weadock relates generally to an anastomosis type staple. Applicant submits that even if Weadock does disclose an anastomosis type staple (e.g., anchoring assembly)



made from bio-absorbable materials, Weadock fails to cure the deficiencies of Yencho in that Weadock does not disclose a flange member and a locking member arrangement, as recited in independent claim 1.

Accordingly, in view of the foregoing, since Weadock fails to cure the deficiencies of Yencho, Applicant submits that claim 16 is allowable under 35 U.S.C. § 103(a) over Yencho in view of Weadock.

Claims 7, and 26-27 stand rejected under 35 U.S.C. § 103(a) over Yencho in view of U.S. Patent No. 6,206,913 to Evard et al. (Applicant presumes that the Examiner intended to refer to 6,616,675 to Evard et al.). Applicant submits that claims 7, and 26-27 are allowable under 35 U.S.C. § 103(a) over Yencho in view of Evard.

The Examiner relies on Evard for the disclosure of a cylindrical body with a taper. Evard relates to various anastomotic connectors and apparatus for forming and/or maintaining connections between openings formed in anatomical structures. However, Applicant submits that even if Evard does disclose a cylindrical member between two flanges wherein the cylindrical body tapers, as recited in claims 7, and 26-27, Evard fails to cure the deficiencies of Yencho in that Evard does not disclose a flange member and a locking member arrangement, as recited in independent claims 1 and 22.

Accordingly, in view of the foregoing, since Evard fails to cure the deficiencies of Yencho, Applicant submits that claims 7, and 26-27 are allowable under 35 U.S.C. § 103(a) over Yencho in view of Evard.

Claims 20-21 stand rejected under 35 U.S.C. § 103(a) over Yencho in view of U.S. Patent No. 5,591,179 to Edelstein. Applicant submits that claims 20-21 are allowable under 35 U.S.C. § 103(a) over Yencho in view of Edelstein.

The Examiner relies on Edelstein for the disclosure of the teaching of a technique of anastomosis in radical prostatectomy. Edelstein relates to a device for deploying a needle and suture to suture the urethral stump and bladder to one another. However, Applicant submits that even if Edelstein does disclose a device for deploying a needle and suture to suture the urethral stump and bladder to one another, as recited in claims 20-21, Edelstein fails to cure the deficiencies of Yencho in that Edelstein does not disclose "advancing the positioning tube through the tubular body to drive and secure the discrete locking member of the anchoring assembly into the annular body of the flange member and to deflect the annular body radially outward," as recited in independent claim 17.

Accordingly, in view of the foregoing, since Edelstein fails to cure the deficiencies of Yencho, Applicant submits that claims 20-21 are allowable under 35 U.S.C. § 103(a) over Yencho in view of Edelstein.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in this application, namely Claims 1-27, are in condition for allowance. Accordingly, early and favorable reconsideration of this application is respectfully requested. Should the Examiner feel that a telephone or personal interview may facilitate resolution of any remaining matters, he or she is respectfully requested to contact Applicant's attorney at the number indicated below.

Application No. 10/516,437  
Amendment dated June 9, 2009  
Reply to Final Office Action of December 10, 2008

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. Sardone', written over a horizontal line.

Francesco Sardone  
Reg. No. 47,918  
Attorney for Applicants(s)

**CARTER, DeLUCA, FARRELL & SCHMIDT, LLP**  
445 Broad Hollow Road, Suite 420  
Melville, New York 11747  
Phone: (631) 501-5700  
Fax: (631) 501-3526